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<p>(21) International Application Number: PCT/DK94/00134</p> <p>(22) International Filing Date: 29 March 1994 (29.03.94)</p> <p>(30) Priority Data: 0393/93 1 April 1993 (01.04.93) DK</p> <p>(71) Applicant (for all designated States except US): MADSEN ELECTRONICS A/S [DK/DK]; Mårkærvej 2A, DK-2630 Taastrup (DK).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): SAXBØL, Morten [DK/DK]; Valgårdsvej 1, 1., DK-2500 Valby (DK). HANSEN, Poul-Erik [DK/DK]; Toggangen 27, DK-2730 Herlev (DK).</p> <p>(74) Agent: LARSEN & BIRKEHOLM A/S SKANDINAVISK PATENTBUREAU; Skagensgade 64, P.O. Box 200, DK-2630 Taastrup (DK).</p>		<p>(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), ES, FI, FI (Utility model), GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, SK (Utility model), UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>In English translation (filed in Danish).</i></p>
(54) Title: PROBE FOR AUDIOMETRIC APPARATUS		
<p>(57) Abstract</p> <p>Probe (1) for an audiometric apparatus (3) to which the probe is coupled by means of a cable (4) and a tube (5). On the tip of the probe there is placed a sealing plug (6) so that the open end (7) of the probe can have acoustic and pressure communication with the blocked area of the person's ear canal (2). The probe (1) comprises a number of parts which can be separated from one another, including the probe tip, which in a simple manner can be removed for replacement or cleaning without this having any influence on the transducers in the probe.</p>		

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PROBE FOR AUDIOMETRIC APPARATUSBackground of the invention

5 The invention relates to a probe for an audiometric apparatus and as disclosed in the preamble to claim 1.

10 Audiometric apparatuses are used for the measuring of various characteristics of a patient's hearing, including the measurement of the characteristics of the eardrum. Thereafter, on the basis of the measurement results, it is possible to diagnose various ailments, hearing deficiencies and so on.

15 An example of such an apparatus is known from USA Patent No. 3,757,769, which enables various electro-acoustic measurements to be carried out. The apparatus has an air pump with which it is possible, via the measuring probe which is placed in the patient's ear canal, to change the pressure in the blocked area of the ear canal between the eardrum and the probe. For this purpose, the probe has three tubes arranged closely together in the manner of a triangle; a tube for regulation of the pressure, a tube for the application of an acoustic signal from a transducer (a loudspeaker), and a tube for acoustic measurement via a second transducer (a microphone). The tip of the probe itself is provided with an ear plug which serves to seal the ear canal, thus enabling the desired degree of sealing to be achieved and therewith the possibility of varying the pressure in the blocked area so that, for example, impedance measurements can be made at the eardrum. A measuring apparatus which carries out acoustic impedance measurements in the ear canal is also called a tympanometer. Such an apparatus can also carry out electro-acoustic measurements other than impedance measurements.

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It is difficult with such an apparatus to carry out measurements on patients who have narrow ear canals, including measurements on children, in that the three tubes which lie closely adjacent to one another simply take up too much space. If tubes with a very small clearance are used to enable a measuring probe to be made for patients with narrow ear canals, various acoustic problems arise and the possibility of errors and inaccuracies in the measurements. Furthermore, it is very difficult to clean the channels in the probe and to keep them clean. When a probe is replaced, an adjustment of the measuring apparatus must be carried out with the new probe, which is very troublesome and costly. Corresponding apparatuses with corresponding drawbacks are known from USA Patent No. 4,057,051 and No. 5,063,946.

In USA Patent No. 4,374,526 there is disclosed a method of measurement and an apparatus for the testing of a person's hearing ability which is based on the finding that sound input to the ear gives rise to a reflected signal from the inner ear which is related to the condition of the inner ear. The apparatus comprises a probe with two transducers, i.e. a pulse generator and a sound detector, said probe being coupled to an electronic apparatus with suitable calculation equipment and so on.

In an article in "Scand Audiol" 11:3-12, 1982 by N.J. Johnsen and C. Elberling, there is described a measuring probe with transducers for use in carrying out measurements as discussed in the above-mentioned USA Patent. The measuring probe comprises a probe tip with sound output from the sound source, and where in the probe there is inserted an acoustic tube having a smaller dimension than the clearance of the probe, said acoustic tube leading to the sound detector. With such a probe it is possible to carry out the measurements which are proposed in USA Patent No.

4,374,526, without the acoustic tubes lying at the side of one another, but such that the one tube surrounds the other.

5 Moreover, it has proved that with a new principle of measurement based on the principle in USA Patent No. 4,374,526, but where the sound signal which is applied to the patient, the so-called stimulus signal, which consists of two substantially sine-waved pulses which lie relatively close to
10 each other as regards frequency, for example so that the one signal has a frequency in the order of 1.1 - 2.0 x the other frequency, it is possible to register other information with relation to the condition in the inner ear. Such acoustic signals can not be applied to a person with the
15 use of the known probes unless these have a total diameter which makes it difficult to carry out measurements on persons with narrow ear canals, among other things because the stimulus signal must be generated by two transducers.

20 In addition to this, the known probes have a number of practical disadvantages, in that they are difficult to clean and to keep clean, the reason being that the probes are built together as one unit and contain electronic transducers and so on which do not readily tolerate cleaning agents, whether or not these are mechanical or chemical
25 cleaning agents. Because of the problems of cleaning etc. between each measurement, the application value of the apparatuses is reduced. Moreover, a very great drawback with all of the known kinds of apparatuses is that the whole of
30 the probe, often coupled together with the cable between the probe and the measuring apparatus, is replaced/exchanged for repair and for particularly thorough cleaning etc., and that the apparatus configuration comprising the apparatus with cable and probe in connection herewith must be
35 re-calibrated, which is time-consuming and costly.

Advantages of the invention

5 The probe according to the invention and as characterized in claim 1 has the advantage that it can be used not only for all of the known electro-acoustic measurements, for example impedance measurements, but also for the measurement of acoustic reflection from the inner ear. The invention makes it possible for the probe to be of very slim configuration and with small dimensions, so that it can be used for measurements even on persons with narrow ear canals, for example babies.

15 The sound canal for the stimulus signal or signals is coupled to the sound tube in the probe in an area of the probe which is arranged to remain outside the ear canal itself, whereby the dimensions of that part of the probe which is to be inserted into the ear canal can be strongly minimized.

20 However, the main advantage of the invention according to claim 1 is that the probe according to the invention is configured so that the whole of the probe tip can be removed for cleaning or replacement. It is hereby possible not only to considerably improve the hygiene when carrying out such electro-acoustic measurements, but it also enables the measuring equipment to be made ready very quickly for the measurement on a new patient by a simple replacement of the probe tip. Consequently, the application value of the apparatus is considerably increased. In practice there is a very great advantage in being able merely to replace the probe tip, in that calibration of the measuring equipment is hereby avoided, which is necessary if the whole of the probe including the transducers are replaced. All of the transducers are arranged in a separate housing, i.e. outside of the probe tip itself, so that cleaning of the probe tip and so on does not damage the transducers, no matter

whether the cleaning is mechanical or chemical. The possibility is also hereby provided of locating possible acoustic filters outside of the probe tip, namely in the transducer housing, so that possible acoustic filters are not influenced or possibly damaged during the cleaning of the probe. This is also contributory to the fact that replacement of the probe tip does not require a new calibration of the measuring apparatus.

It is preferable that the input canals for the stimulus signal or signals form an angle with the longitudinal axis of the probe, i.e. preferably an acute angle with the probe tip as disclosed in claim 2.

By configuring the probe according to the invention as disclosed in the embodiment characterized in claim 3, a further advantage is provided in that the sound canals can be cleaned, for example of ear wax and the like, and the sound tube can be replaced, for example by a tube with another clearance for other measurements, or it can simply be replaced instead of cleaned.

By configuring the probe according to the invention as disclosed and characterized in claim 4, the input canals are made to open out in the sound canal at a distance from the probe tip, whereby in addition to the above-mentioned advantages, various acoustic advantages can be achieved, for example an increased possibility of suppressing coupling between the transducers.

By configuring the probe according to the invention as disclosed and characterized in claim 5, the probe contains all necessary canals in integrated form, which makes it possible with the probe and suitable measuring equipment to carry out all known electro-acoustic measurements which can be effected via the ear canal.

At the same time, the possibility is hereby provided of reducing the production costs of the probe, in that the probe, or at least those parts which are to be capable of replacement, namely the probe tip with sound detector tube, 5 can be produced by moulding, for example injection moulding in plastic. It is naturally also possible to produce the other parts of the probe by moulding or injection moulding in plastic, but it is of special significance that the 10 probe tip and the sound detector tube can be produced cheaply by mass production, in that these are the parts which must be capable of being removed for frequent cleaning or possible replacement.

15 According to another embodiment of the invention, and as disclosed and characterized in claim 6, the probe tip is provided with inlaid sound tubes. This enables a reduction to be achieved in the acoustic separation between the sound source(s) and the sound detector, so that even better measuring results can be achieved, the reason being that the 20 mutual coupling is reduced.

A further improvement in the acoustic characteristics can be achieved by configuring the sound tube(s) as disclosed 25 and characterized in claim 7, in that this hereby introduces a pressure drop from the mouth of the sound tubes to the mouth of the sound detector.

By configuring the probe according to the invention as 30 disclosed and characterized in claim 8, security is provided that the parts are always coupled correctly, in that the cooperating means are preferably configured so that the coupling together is not possible unless the parts are correctly positioned in relation to one another. The parts can 35 consist of one or more guide pins or the like, preferably arranged on the transducer housing, with said guide pins

being arranged to enter into engagement with suitable holes in the probe tip.

5 By configuring the probe according to the invention as disclosed and characterized in claim 9, the possibility is provided of improving the transfer of acoustic signals from the blocked area in the ear canal to the sound detector. It is also possible hereby to improve the acoustic adaptation between the parts. This is important, the reason being that
10 the signals to be monitored and measured are at relatively low levels.

Finally, the probe according to the invention can be configured as disclosed and characterized in claim 10. The
15 probe is hereby easy to dismantle, and it is thus also easy to replace individual parts in the probe. The parts are naturally configured in such a way that they fit immediately together and can only be assembled in the correct manner.

20

The drawing

Two example embodiments according to the invention are shown in the drawing and are explained in more detail in
25 the following description, in that

fig. 1 shows a measurement situation with an audiometric apparatus and probe according to the invention, where the probe is shown substantially to scale,
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fig. 2 shows an exploded view of the probe itself according to a first embodiment and shown on a larger scale,

35 fig. 3 shows a sound detector tube in fig. 2 in section and seen from outside,

- fig. 4 shows a plane section of the probe tip in fig. 2 in the plane IV-IV in fig. 5,
- 5 fig. 5 shows the probe tip in fig. 2 seen in the direction V-V in fig. 4,
- fig. 6 shows a plane section of the probe tip in fig. 2 in the plane VI-VI in fig. 5 and with sound detector tube inserted,
- 10 fig. 7 shows a plane section of the transducer housing in fig. 9 in the plane VII-VII,
- 15 fig. 8 shows a plane section of the transducer housing in fig. 9 in the plane VIII-VIII,
- fig. 9 shows the transducer housing seen in the direction IX-IX in fig. 7,
- 20 fig. 10 shows a plane section of a second embodiment according to the invention, i.e. the section X-X in the probe tip in fig. 11, and
- 25 fig. 11 shows the probe tip in fig. 10 seen in the direction XI-XI.

Description of the example embodiments

- 30 In fig. 1 is seen the execution of an audiometric measurement, in that a measuring apparatus 3, via a cable and a measuring probe 1, is used for electro-acoustic measurements via the ear canal 2 of a person.
- 35 At the end of the probe, the ear canal is blocked by means of a sealing plug 6 which is used for the cancellation of

differences in the ear canals of different persons. There is thus a blocked area in the ear canal 2 between the probe 1 with sealing plug 6 and the ear drum of the person.

5 In order to be able to change the pressure in the blocked area, there is also a tube 5 leading from the measuring apparatus 3 to the probe 1, for example a thin plastic tube, hereby enabling the pressure in the blocked area of the ear canal to be equalized or changed.

10

The probe has a tip with an open end 7 directed in towards the blocked area and the eardrum. In the probe itself are placed the transducers necessary for carrying out various forms of electro-acoustic measurement, or such that measurements of the kind described in the earlier-mentioned USA Patent No. 4,374,526 and the article from "Scand Audiol" can also be carried out.

20 Fig. 2 shows an exploded view of the probe, and it will be seen that in the embodiment shown the probe consists of five parts, i.e. a probe tip 11 which can accommodate a sound detector tube 12 and which is thereafter secured to a transducer housing 13 by means of a union 10 which is screwed on to the thread 44 on the transducer housing. The probe concludes with a cap 14 having load relief 15 for the cable and an outlet 16 for the cable 5.

30 The most essential parts of the first embodiment according to the invention, i.e. the sound detector tube 12, the probe tip 11 and the transducer housing 13, will now be described in more detail with reference to figs. 3-9 of the drawing.

35 Fig. 3 shows the sound detector tube 12, which consists of a tubular part 20 which terminates in a conical part 21. The sound detector tube is arranged to be placed inside the

probe tip as shown in fig. 6. The sound detector tube 12 can have an increasing clearance, for example so that the clearance increases stepwise from the section 22 with small clearance to the section 23 with larger clearance, and to the outlet section 24 with the largest clearance.

The probe tip is seen in figs. 4-6, and in fig. 6 the probe tip is shown with the sound detector tube inserted. In the probe tip there is a central opening 28, a so-called sound canal, which accomodates the sound detector tube, and which in the annular area between the sound detector tube and the probe is arranged to transfer the stimulus signal or signals from the transducers in the transducer housing to the open end 7 of the probe.

The probe tip 11 comprises three canals, all of which form an acute angle to the axis of the probe tip. Two of the canals 26 are so-called supply canals for stimulus signals, and the third canal 27 is intended for pressure equalization or regulation of the pressure in the sealed area in the ear canal. The canals open out in an area 31 at that end of the sound detector tube 12 which faces away from the probe tip 11. In the embodiment shown, the stimulus canals 26 lie diagonally opposite one another, so that they also open out opposite one another but on each their side of the sound detector tube, so that the openings in the canals 26 cannot "see" each other.

Further to this, the probe tip has two blind holes 30 which are arranged to engage with guide pins on the transducer housing, which is explained later. The probe tip is further arranged in such a manner that the opening 29 for insertion of the sound detector tube 12 is of such a dimension that there remains a circular area below the tube 12 for engagement with a corresponding, forwardly-facing raised portion on the transducer housing. Furthermore, the probe tip 11

comprises an annular flange 32 which is arranged to lie up against a correspondingly annular surface on the transducer housing.

5 The probe tip 11 is also configured with reduced dimensions and thickness 42, 43 in the direction towards the open end 7 of the probe, as shown in fig. 4.

10 Figs. 7-9 show the transducer housing, which comprises a cavity 39 for insertion of the cables and tubing. The tubing is connected in a known manner with the canal 38, which lies directly opposite the opening of the canal 27 in the probe tip. Moreover, the transducer housing has two areas 34 for electro-acoustic transducers, so-called miniature
15 signal generators, which via the sound canals 35 can conduct the stimulus signals to the canals 26. Finally, the transducer housing comprises a central area 36 for a sound detector transducer, a so-called miniature microphone, which via a short sound canal 37 on the raised portion 41
20 is arranged to be coupled to the opening in the sound detector tube 12 in the probe tip 11.

The transducer housing has two guide pins or raised portions 33 which can be an integral part of the rest of the
25 transducer housing, or which can be separate pins inserted in blind holes in the transducer housing. It will be seen clearly from figs. 7 and 8 that the transducer housing with raised portion 41 fits immediately into the opening 32, 29 in the probe tip, so that all the canal connections can be
30 established with suitable tightness and acoustic connection.

The probe 1 can thus house two transducers for the generation of stimulus signals in the areas 34, and a sound detector transducer in the area 36. The canals 35 can be provided with suitable acoustic filters. The sound canals 26
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for the stimulus signals are preferably arranged opposite each other as shown, so that the two transducers associated herewith or the signals from said transducers do not give rise to any mutual coupling or any other kind of influence on each other.

With the embodiment of the probe 11' as shown in figs. 10 and 11, it is possible for the sound detector tube 12 shown in figs. 2 and 3 to be omitted. When the embodiment shown in figs. 10 and 11 is used, the probe tip 11 on the sound detector tube 12 in fig. 2 is thus replaced by the probe tip 11'. The probe tip 11' has a central sound detector canal 54 which, via the opening 29', is coupled to the area 36 in the transducer housing 13, see figs. 7 and 8. In each of the sound canals 26', which open out in a common sound canal 28', there is placed a sound tube 50, 51 of soft plastic, rubber or similar suitable material. The thin-walled area 42' of the probe tip 11' ends with an annular, preferably circular opening 53. The sound tubes 50, 51 are preferably slightly longer than the probe tip, so that their openings 52 are in the order of 0.5-5 mm outside the opening 53 in the probe tip. The resulting embodiment is thus one without the sound detector tube 12, but actually with better acoustic characteristics because of the sound tubes 50, 51, and with the possibility of configuration with various acoustic characteristics, partly by using different materials and partly by changing the length of the sound tubes. Mutual coupling between the transducers, especially coupling from the signal generators to the sound detector, is hereby avoided, the reason being that there will be a drop in pressure from the openings 52 to the opening 53.

The probe tip 11' has holes 30' for engagement with and guidance of the pins 33 in the transducer housing 13, and canal openings 26' and 27' corresponding to the probe tip

11 in the first embodiment.

5 It will be obvious to those skilled in the art that probe tips other than those shown will be able to be configured within the scope of the invention, and be mounted in the probe according to the invention and hereby achieve the desired effects.

10

C L A I M S

1. Probe (1) for audiometric apparatus for the examination of the hearing etc., said probe having a probe tip (11, 11') which is arranged to be inserted in a person's ear canal (2), and where the probe has an open end (7) in the direction towards the person's eardrum, said probe comprising an area (36) for at least one sound detector with a central sound detector canal (28, 28', 12, 54) and at least one area (34) for at least one signal generator and a corresponding sound canal (26, 26', 28, 28'), characterized in that the probe tip (11) constitutes an independent, replaceable unit arranged to be coupled together with a transducer housing (13) which has areas (34, 36) for the mounting of transducers for the conversion of electric signals to acoustic signals and vice versa, and with means (30, 30') which ensure the correct coupling together of the sound canal (28, 28', 54) with the sound detector as well as correct coupling together of the sound canal or sound canals (26, 26') with the signal generator or signal generators.
2. Probe according to claim 1, characterized in that the sound canal or canals (26, 26') form an angle with the probe's longitudinal axis of 5-80°, preferably 10-40°.
3. Probe according to claim 1, characterized in that the sound detector canal constitutes an independent sound tube (12) which is mounted in the probe tip (11) in the probe (1) in a removable manner.
4. Probe according to claim 1 or 2, characterized in that the sound canals (26) open out in the probe in an area (31) in the vicinity of that end of the sound tube (12) which is opposite the open end (7) of the

probe.

5 5. Probe according to claim 1, characterized
in that the probe tip (11) further comprises a canal (27,
27') which opens out in the sound canal (28, 28') and is
arranged for pressure communication between the area in the
ear canal (2) which is blocked by the probe (1) and the
surroundings and/or a measuring apparatus (3) for the ad-
justment of the pressure in the ear canal, and in that the
10 probe tip is configured as one unit of plastic, for example
by moulding.

15 6. Probe according to any of the claims 1-5, characterized
in that each of the sound detector canals
(26') is arranged for the mounting of at least one sound
tube (50, 51), which via the sound canal (28') extends to
the area around the open end (7) of the probe.

20 7. Probe according to claim 6, characterized
in that the length of each of the sound tubes (50, 51) is
such that they extend slightly beyond the opening (53) at
the open end (7) of the sound canal (28').

25 8. Probe according to claim 1, characterized
in that the transducer housing (13) is configured as an in-
dependent unit arranged for coupling together with the
probe tip (11), and comprises means (33) for cooperation
with the means (30, 30') on the probe tip (11, 11') for
correct coupling.

30 9. Probe according to claim 3, characterized
in that the sound tube (12) has increasing clearance (23,
24, 25) in the direction towards the open end (7) of the
probe.

35 10. Probe (1) for audiometric apparatus (3) for the exam-

ination of the hearing etc., said probe being arranged to be inserted in a person's ear canal (2), for example using a sealing plug against the ear canal, and where the probe has an open end (7) in the direction towards the person's eardrum, said probe comprising transducers which are coupled to the audiometric apparatus (3) via a cable (4), characterized in that the probe comprises a transducer housing (13) with an annular threaded area (44) for the mounting of a union piece (10) with corresponding thread, in that said union separably secures a replaceable probe tip (11, 11').

15

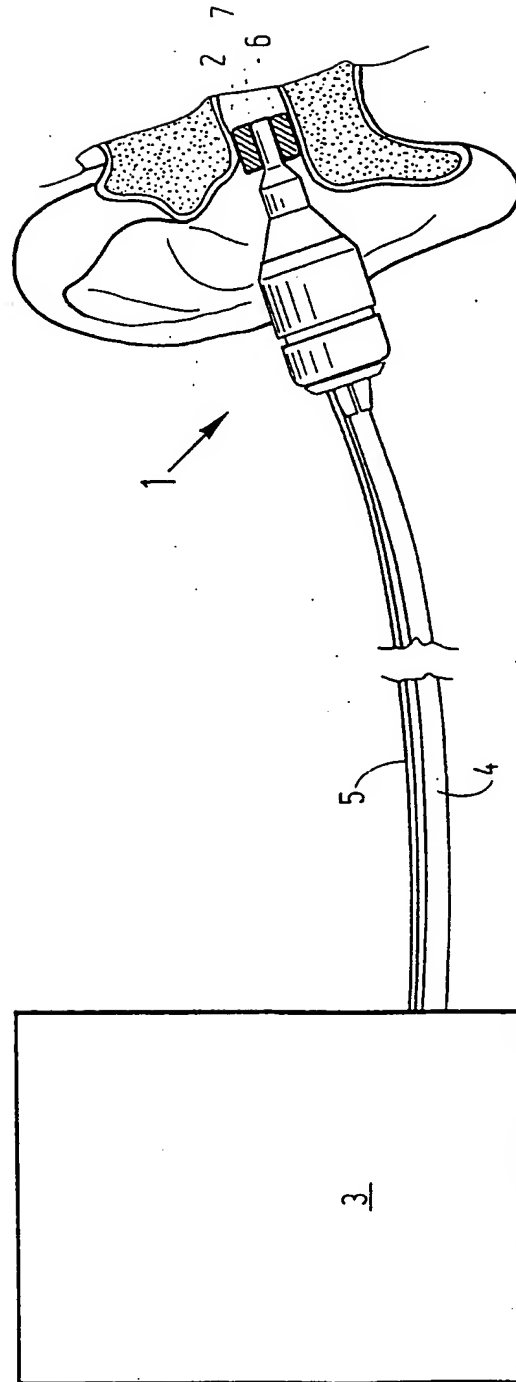
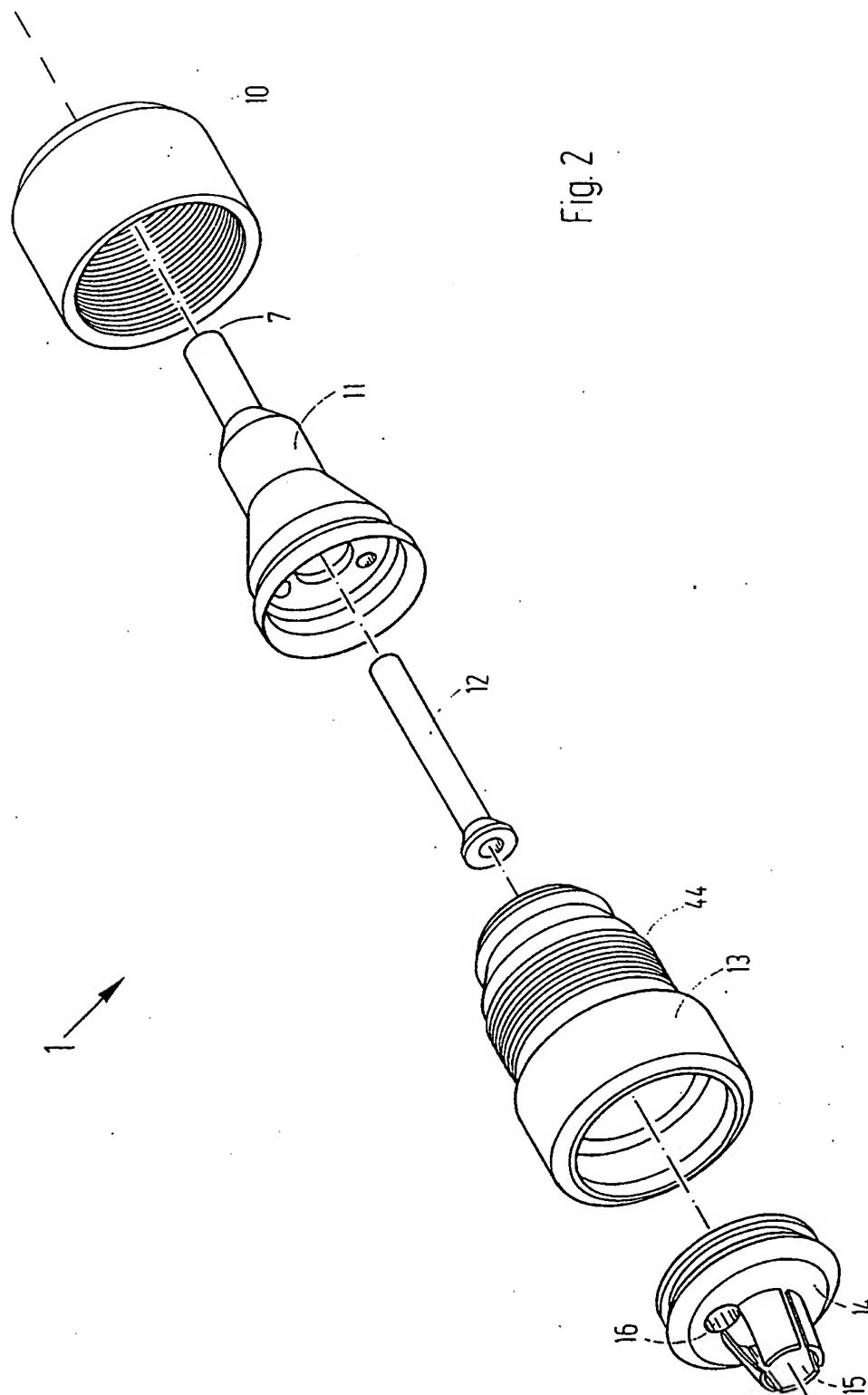


Fig.1

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Fig. 2



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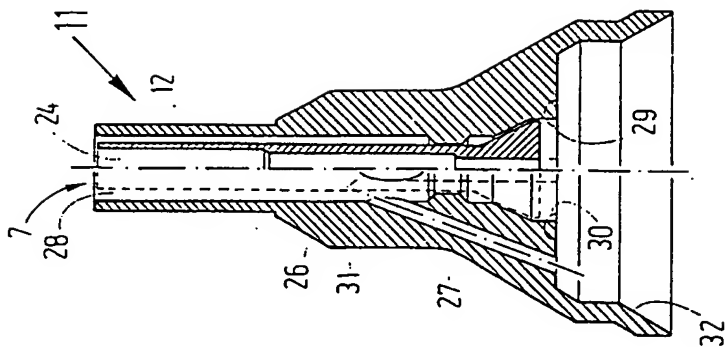


Fig. 6

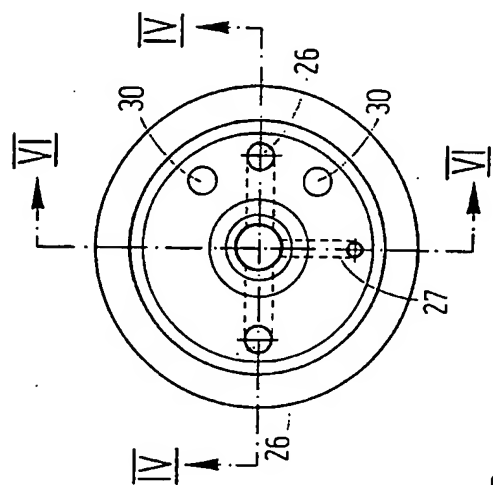


Fig. 5

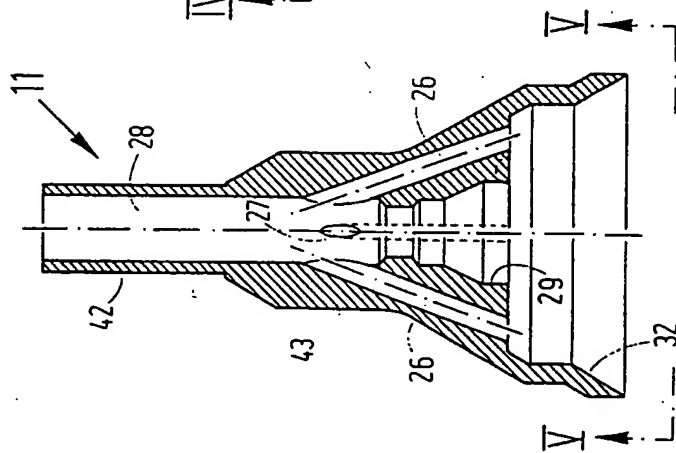


Fig. 4

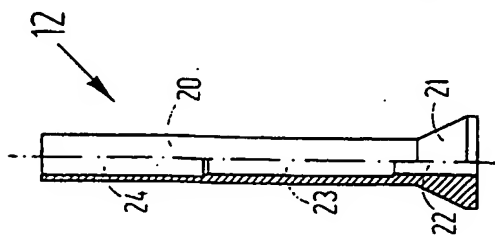


Fig. 3

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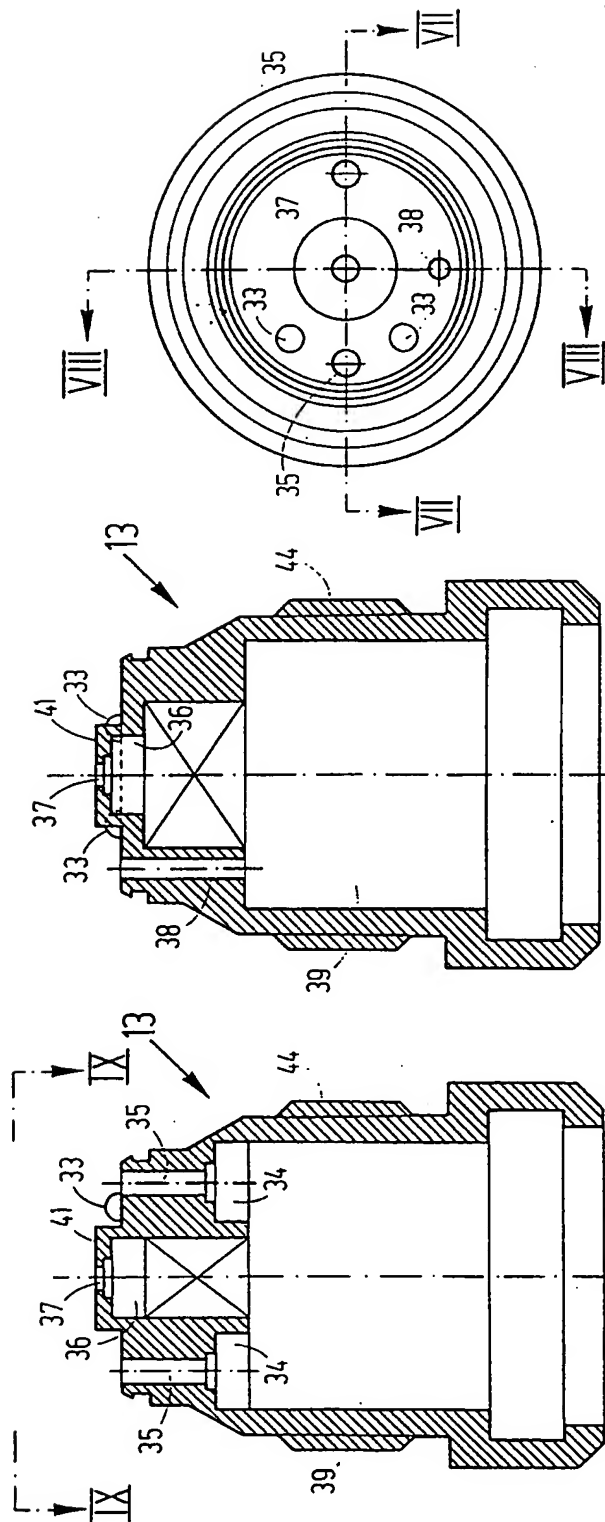


Fig. 9

Fig. 8

Fig. 7

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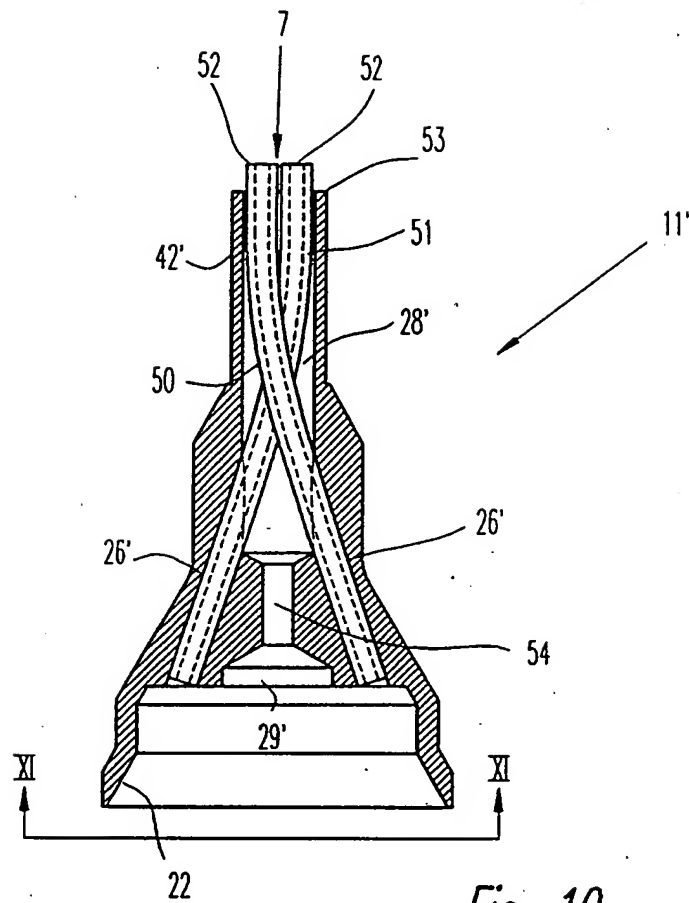


Fig. 10

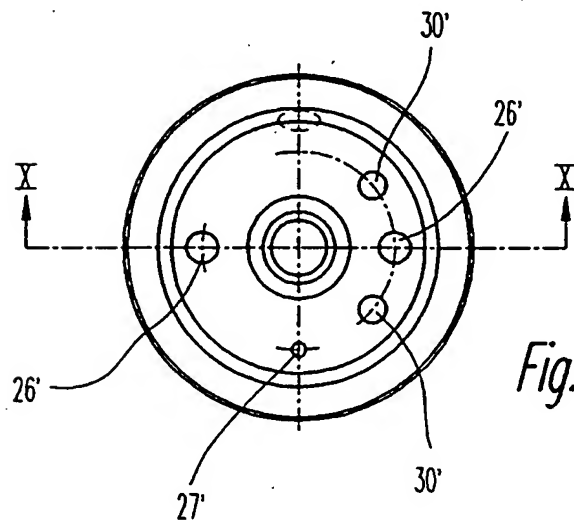


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00134

A. CLASSIFICATION OF SUBJECT MATTER

IPC : A61B 5/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC : A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4057051 (ADRIAN R. KEROUAC), 8 November 1977 (08.11.77), see the whole document --	1-10
A	US, A, 3757769 (LAWRENCE B. ARGUIMBAU ET AL), 11 Sept 1973 (11.09.73), see the whole document --	
A	US, A, 4374526 (DAVID T. KEMP), 22 February 1983 (22.02.83), see the whole document --	
A	US, A, 5063946 (HIROSHI WADA), 12 November 1991 (12.11.91), see the whole document -- -----	



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